Modified PTO/SB/33 (10-05)

PRE-APPEAL BRIEF REQUEST FOR REVIEW	Docket Number Q88123	
Mail Stop AF Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Application Number 10/537,462	Filed June 3, 2005
	First Named Inventor Kenji MATSUDA	
	Art Unit 1617	Examiner Layla Soroush

WASHINGTON OFFICE
23373
CUSTOMER NUMBER

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal

The review is requested for the reasons(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

☑ I am an attorney or agent of record.
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June 1, 2007
Date

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	Docket No: Q88123
Kenji MATSUDA, et al.	
Appln. No.: 10/537,462	Group Art Unit: 1617
Confirmation No.: 4737	Examiner: Layla Soroush

Filed: June 3, 2005

For: PROPOFOL-CONTAINING FAT EMULSIONS

PRE-APPEAL BRIEF REQUEST FOR REVIEW

MAIL STOP AF - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to the Pre-Appeal Brief Conference Pilot Program, and further to the Examiner's Final Office Action dated December 1, 2006, Applicant files this Pre-Appeal Brief Request for Review. This Request is also accompanied by the filing of a Notice of Appeal.

Applicant turns now to the rejections at issue: (1) claims 1-4, 13, 15, 16, 18-20, 29, 31 and 32 are rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by Yamada et al (publication, June 26, 2002; JP '562), as evidenced by PDRHealth; (2) claims 5, 7-9, 11, 12, 21, 23-25, 27, 28 and 33 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over JP '562, as evidenced by PDRHealth, and further in view of Unger et al (USP 6,090,800); and (3) claim 17 remains rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over JP '562 and further in view of Yugari (US 2001/0047162).

Applicants respectfully traverse the rejection for the reasons of record and for the following reasons.

The Examiner takes the position that the PDRHealth reference discloses that phosphatidylcholine comprises the fatty acids of component (c) and asserts that "It is well-known in the art that egg lecithin comprises phospholipids, such as phosphatidylcholine, and saturated and unsaturated fatty acids inclusive of those recited in component (c)". In addition, the Examiner appears to consider Example 1 of JP '562 as teaching: Lidocaine (local anesthetic), propofol, soy bean oil (oily component), yolk lecithin (stabilizer and emulsifier), and polyoxyethylene (60) hydrogenated castor oil (emulsifier).

However, the stabilizers utilized in the examples and described (having HLB of 10 or more) in JP '562, i.e., polyoxyethylene (HCO-60) (HLB 14), (60) hydrogenated castor oil sodium lauryl sulfate (HLB 40), polysorbate (HLB 15), mono-coconut acid polyoxy (HLB 17), ethylene sorbitan mono lauric acid deca glyceryl (HLB 15.5) and polyoxyethylene (HLB 16), do not meet the requirements of (a) to (d) recited in the present claims.

In addition, phosphatidylcholine is different from claimed components (a) and (b). Also, egg lecithin is not a fatty acid selected from the group consisting of C_{10-22} linear or branched, saturated or unsaturated fatty acids (component (c)). The Examiner asserts that egg lecithin comprises fatty acids, however, such is not the case. To the contrary, R and R_1 in a chemical formula of phosphatidylcholine shown in the PDRhealth reference are not fatty acids, but are recited as fatty acid residues, which bond to a main chain by ester linkages. Thus, phosphatidylcholine and phosphatidylcholine is clearly different from claimed component (c) in

that the former is not a fatty acid that has a terminal carboxyl radical (COOH). *See e.g.,* Examples of the specification.

In addition, if fatty acids are comprised as impurities, the amount would be far too small to effectively function as a stabilizer. For example, in Example 1 of JP '562, "purified yolk lecithin" was used. Since yolk lecithin with a high purity was used, an impurity content must be extremely small in comparison with typical egg lecithin. Given this, the propofol-containing fat emulsion described in Example 1 of JP '562 does not comprise fatty acids in the concentration range recited in claim 1.

For the above reasons, egg lecithin does not qualify as a stabilizer within the scope of claims 1, 18 and 33, and JP '562 does not disclose a propofol-containing fat emulsion which satisfies the requirement of claims 1, 18 and 33.

Further, with respect to the phospholipids having specific numbers of carbon atoms recited in claim 5, the Examiner asserts that Unger discloses distearoylphosphatidylglycerol, palmitic acid, stearic acid, oleic acid, dioleylphosphatidylethanolamine, distearoylphosphatidylethanol-amine-polyethylene glycol 5000, etc. as examples of stabilizers for pharmaceutical compositions.

Unger describes that the above components are useful as stabilizers, but does not provide any guidance or advantages in selecting those specific stabilizers among the numerous stabilizers exemplified in Unger. However, Unger does not disclose a specific fat emulsion containing propofol, an oily component, and an emulsifier, as a pharmaceutical composition that can contain such stabilizers. Usefulness of an emulsifier must be determined in the relationship

with other components, and a specific substance can not be said to be useful as an emulsifier for all pharmaceutical compositions without considering other components and the state of a composition.

Therefore, it is submitted that it is unpredictable and there is no reasonable expectation based on the disclosure of Unger that the stabilizers described in Unger would provide sufficient emulsion stability in a specific fat emulsion comprising propofol, an oily component, and an emulsifier, when a local anesthetic is admixed.

Furthermore, JP '562 discloses a fat emulsion comprising an O/W-type emulsion containing propofol and lidocaine; it merely discloses a hydrophilic surfactant of 10 or more HLB as a stabilizer. Table 1 of JP '562 presenting the stability test results of some stabilizers does not include stabilizers (a) to (d) used in the present invention, which are completely different from the hydrophilic surfactants of 10 or more HLB, or any compounds analogous thereto. Accordingly, it is respectfully submitted that it would not have been obvious to one of ordinary skill in the art to substitute the stabilizer of Unger for that in the composition of JP '562.

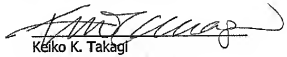
Moreover, even if JP '562 and Unger were somehow combined, one of ordinary skill in the art would not expect the superior results provided by the present invention as a result of selecting a specific compound from the wide range of stabilizers disclosed by Unger and substituting the surfactant disclosed in JP '562 with the compound.

For the foregoing reasons, it is respectfully submitted that claims 1-5, 7-9, 11-13, 15-21, 23-25, 27-29 and 31-33 are patentable over the cited art.

Accordingly, Appellants respectfully request the Pre-Appeal Brief Conference Panel to

withdraw the foregoing rejections.

Respectfully submitted,



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